Declaration of Product Conformity:
Validation of PriMed Instruments RCB IFU

Product Family: Reusable Cleaning Brushes – RCB (all 8000 Series models)

PriMed Instruments Inc. sponsored HIGHPOWER Validation Testing & Lab Services to conduct testing to validate the cleaning, sterilization and multiple reprocessing of our Reusable Cleaning Brushes (RCB) as described in W-7.5.3-W4 – RCB IFU[(1)]. Validation was done according to instructions provided in the IFU and method outlined in AAMI TIR12[(6)] and TIR30[(7)]. HighPower's cleaning studies[(2)(3)] confirmed that our IFU cleaning instructions were efficacious in removing gross amounts of soil from our RCB to a TOC level of less than 2.2µg/cm^2 and protein level of less than 6.4µg/cm^2. HighPower's sterility studies[(4)(5)] provided evidences that the CIDEX® solution and steam sterilization parameters recommended in our IFU achieved a 10^{-6} sterility assurance level when sterilizing our RCB.

Date of Declaration: Feb. 20, 2014

Declared at: Mississauga, Ontario, Canada

Authorized By (Signature): _____

Authorized By (Print): Dung Ly

Manager of Regulatory Affairs, PriMed Instruments Inc.

References:

[1] PriMed Instruments Doc ID: Instructions for Use W-7.5.3-W4 – RCB IFU, Revised and Approved 2014/01/31.

[2] HIGHPOWER Study No. 1308-410, Protocol and Final Report titled "Manual Cleaning Validation of the PriMed Reusable Cleaning Brushes Protein Analysis", Feb. 2014.

[3] HIGHPOWER Study No. 1308-410-1, Protocol and Final Report titled "Manual Cleaning Validation of the PriMed Reusable Cleaning Brushes Total Organic Carbon (TOC) Analysis", Feb, 2014.

[4] HIGHPOWER Study No. 1308-411 Revision A, Protocol and Final Report titled "Sterilization Efficacy Validation of the PriMed Reusable Cleaning Brushes Steam Pre-Vacuum", Dec. 2013.

[5] HIGHPOWER Study No. 1308-412 Revision A, Protocol and Final Report titled "Sterilization Efficacy Validation of the PriMed Reusable Cleaning Brushes with CIDEX® Solution", Dec. 2013.

[6] AAMI TIR12:2010 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device Manufacturers.

[7] AAMI TIR30:2011 A compendium of processes, materials, test methods and acceptance criteria for cleaning reusable medical devices.

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